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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,465	07/28/2000	Tim Keith	Hum00-23	2776

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EXAMINER

EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 02/10/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/627,465

Applicant(s)

KEITH, TIM

Examiner

Juliet C Einsmann

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-19, 22-26, 28-42, 46, 48, 50, 52-54, 56-64, 68, 70 and 72 is/are pending in the application.
- 4a) Of the above claim(s) 16-19, 22-26 and 28-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-42, 46, 48, 50, 52-54, 56-64, 68, 70 and 72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. This action is written in response to applicant's correspondence submitted 1/27/02 paper number 16. Claims 34, 37-38, 42, 46, 48, 52-54, 56, 59-60, 64, 68, 70, and 72 have been amended and claims 43-45, 47, 49, 51, 55, 65-67, 69, 71, and 73-74 have been canceled. Claims 16-19, 22-26, 28-33, 34-42, 46, 48, 50, 52, 53, 54, 56-64, 68, 70, and 72 are pending.

Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.**

2. This application contains claims 16-19, 22-26, and 28-33 drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application 60/146336 (filed 7/30/99) upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 34-42, 46, 48, 50, 52, 53, 54, 56-64, 68, 70 and 72 of this application. The priority document does not appear to disclose an isolated nucleic acid molecule comprising SEQ ID NO: 1 or SEQ ID NO: 2. The priority document does not appear to provide support for claims which claim these sequences or nucleic acids comprising 289 contiguous nucleotides of these sequences. Furthermore, the priority document does not provide disclosure of the oligonucleotides recited in claims 52-53 because the

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priority document does not disclose the polymorphisms taught in Table 5 of the instant specification. Thus, priority has not been granted to the date of 7/30/99.

Claim Rejections - 35 USC § 102

4. Claims 34-38, 41, 42, 46, 48, 50, 52, 53, 54, 56-60, 63, 64, 68, 70 and 72 are rejected under 35 U.S.C. 102(b) and under 35 U.S.C. 102(a) as being anticipated by GenBank Accession AI126846 (GI: 3595360, 26 October 1998).

The instant application claims priority to provisional application 60/146336, filed 7/30/99. However, priority is not granted to this date (see previous section of office action under heading "Priority."). Thus, this GenBank record is a 102(b) type reference. This reference is also available under 102(a). It is applied to these claims under both statutes.

The GenBank record provides an isolated nucleic acid molecule comprising a nucleotide sequence comprising 289 or more contiguous nucleotides of SEQ ID NO: 1. In particular, nucleotides 1-450 of the sequence taught in the GenBank record are identical to nucleotides 6688-7137 of instant SEQ ID NO: 1. The GenBank record teaches that this nucleic acid was contained in a pT7T3D expression vector with a modified polylinker and that the lab host was ampicillin DH10B cells. DH10B cells are *E. coli* cells, and thus are a prokaryotic host cell.

The isolate nucleic acid provided in the GenBank record comprises 39 contiguous nucleotides of SEQ ID NO: 48. Specifically, nucleotides 271-309 of the GenBank record are identical to nucleotides 1-39 of SEQ ID NO: 48 (which is SEQ ID NO: 48 in its entirety).

The isolated nucleic acid taught in the GenBank record comprises 40 or more contiguous nucleotides of SEQ ID NO: 1 and includes a single nucleotide polymorphism that is a C at position 6991.

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The GenBank record provides an isolated nucleic acid molecule comprising a nucleotide sequence comprising 289 or more contiguous nucleotides of SEQ ID NO: 2. In particular, nucleotides 25-316 of the sequence taught in the GenBank record are identical to nucleotides 1266-1557 of instant SEQ ID NO: 2 (292 identical nucleotides in total). The GenBank record teaches that this nucleic acid was contained in a pT7T3D expression vector with a modified polylinker and that the lab host was ampicillin DH10B cells. DH10B cells are *E. coli* cells, and thus are a prokaryotic host cell.

Claim Rejections - 35 USC § 103

5. Claims 39, 40, 61, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over GenBank Accession AI126846 (GI: 3595360, 26 October 1998) in view of Lasky *et al.* (US 5304640).

The GenBank record provides an isolated nucleic acid molecule comprising a nucleotide sequence comprising 289 or more contiguous nucleotides of SEQ ID NO: 1. In particular, nucleotides 1-450 of the sequence taught in the GenBank record are identical to nucleotides 6688-7137 of instant SEQ ID NO: 1. The GenBank record teaches that this nucleic acid was contained in a pT7T3D expression vector with a modified polylinker and that the lab host was ampicillin DH10B cells. DH10B cells are *E. coli* cells, and thus are a prokaryotic host cell.

The GenBank record provides an isolated nucleic acid molecule comprising a nucleotide sequence comprising 289 or more contiguous nucleotides of SEQ ID NO: 2. In particular, nucleotides 25-316 of the sequence taught in the GenBank record are identical to nucleotides 1266-1557 of instant SEQ ID NO: 2 (292 identical nucleotides in total). The GenBank record

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teaches that this nucleic acid was contained in a pT7T3D expression vector with a modified polylinker and that the lab host was ampicillin DH10B cells. DH10B cells are *E. coli* cells, and thus are a prokaryotic host cell.

The GenBank record does not teach eukaryotic or human host cells.

However, at the time the invention was made, the transformation of human host cells (which are eukaryotic host cells) with vectors comprising nucleic acids encoding human proteins was routine in the art. Lasky *et al.* teach "Typical eukaryotic host cells are mammalian, such as Chinese hamster ovary cells or human embryonic kidney 293 cells (Col. 11, lines 36-38)." Therefore, It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have transformed human host cells with vectors comprising the nucleic acid taught by the GenBank record. The ordinary practitioner would have been motivated to create such host cells for the benefit of expression the polypeptide encoded by the nucleic acid taught by the GenBank record in order to characterize and study the polypeptide.

Response to Remarks

The objection to the claims is withdrawn in view of applicant's amendment removing the references to the tables from the claims and canceling claim 74.

The rejections under 112 2nd paragraph are withdrawn in view of applicant's amendments to the rejected claims and/or applicant's cancellation of the rejected claims.

All previous rejections under 35 U.S.C. 102 are withdrawn in light of applicant's amendments to the claims or in light of applicant's arguments. New rejections are set forth to address applicant's amendments to the claims.

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The rejection in view of Shankar *et al.* is overcome because the longest stretch of contiguous nucleic acids taught by Shankar *et al.* in common with SEQ ID NO: 1 or SEQ ID NO: 2 is 243 nucleotides. The examiner's previous statement that Shankar *et al.* comprises a longer stretch of nucleic acids identical to SEQ ID NO: 1 or SEQ ID NO: 2 was in error because a careful review of the alignments that were provided shows that there is a single nucleotide gap and nucleotide 814. The rejection of the claims as being anticipated by the BACPAC filters is withdrawn in view of applicant's disclosure of an "isolated" nucleic acid in the specification. The remaining 102 rejections are overcome in view of the amendments to the claims. All previous rejections under 35 U.S.C. 103 are withdrawn in light of applicant's amendments to the claims.

Conclusion

6. No claims are allowed.
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Claims drawn to an isolated nucleic acid comprising SEQ ID NO: 1 or the complement of SEQ ID NO: 1 would be allowable. Claims drawn to an isolated nucleic acid consisting of SEQ ID NO: 2 or the complement of SEQ ID NO: 2 would be allowable.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Juliet C Einsmann
Examiner
Art Unit 1634

February 4, 2003


JEFFREY FREDMAN
PRIMARY EXAMINER